

Citation:

Buscemi S, Verga S, Tranchina MR, Cottone S, Cerasola G. Effects of hypocaloric very-low-carbohydrate diet vs. Mediterranean diet on endothelial function in obese women. *Eur J Clin Invest*. 2009 May; 39 (5): 339-347.

PubMed ID: [19302563](#)

Study Design:

Randomized Controlled Trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the effect of diet on weight and endothelial function using two hypocaloric diets, a very low-carbohydrate (CHO) diet and a Mediterranean diet.

Inclusion Criteria:

- Females
- Ages 30-50 years
- Body Mass Index (BMI) from 27-39.9kg/m².

Exclusion Criteria:

Metabolic, cardiovascular, systemic diseases or any drug treatment.

Description of Study Protocol:**Recruitment**

Not described.

Design

Longitudinal, randomized controlled, open study design.

Dietary Intake/Dietary Assessment Methodology

Adherence to the study diets was assessed using three-day food records collected every two weeks throughout the study.

Blinding Used

Not applicable.

Intervention

- Subjects were assigned to follow either the Atkins low-CHO diet or the Mediterranean hypocaloric diet for two months
 - The Atkins diet had 5% CHO, 25% fat, 30% protein during the first two weeks and 20% CHO, 55% fat and 30% protein during the remainder of the study
 - The Mediterranean diet had 55% CHO, 25% fat and 20% protein
- All subjects were prescribed a diet program that had 20kcal/kg of body weight
- Subjects met with a registered dietitian weekly and received nutritional counseling
- Participants were asked to maintain their usual physical activity level.

Statistical Analysis

- An expected difference in flow-mediated dilation within each group due to dietary effect was estimated to be 5%. The power analysis showed that with an α of 0.05 and a power of 82-94%, seven to 10 subjects were needed per group
- The effect of the dietary intervention was assessed by using repeated-measures ANOVA with time as the within-subject factor and diet as the between-subjects factor. Bonferroni T-test was performed for individual differences between two time points when appropriate.
- One-way ANOVA was used to compare diet group characteristics at each time point
- $P < 0.05$ was considered statistically significant.

Data Collection Summary:

Timing of Measurements

- Subjects followed their assigned diets for two months
- Anthropometric measurements, dietary intake data, urinary ketone concentrations and blood samples were collected at baseline and every two weeks.

Dependent Variables

- Weight was measured by study personnel
- Body composition was measured using bioelectrical impedance
- Flow-mediated dilation was measured in the brachial artery using high-resolution vascular ultrasound
- Plasma glucose, triglycerides, cholesterol, HDL-cholesterol, LDL-cholesterol, HOMA-IR and insulin were measured using fasting blood draws.

Independent Variables

Diet group: Dietary intake data was collected using three-day food records.

Control Variables

Not applicable.

Description of Actual Data Sample:

- *Initial N*: N=25 women

- *Attrition (final N)*: N=20 women, with 10 subjects in each diet group
- *Age*: Low-CHO diet group: 38±3 years; Mediterranean diet group: 39±3 years
- *Ethnicity*: Not described
- *Other relevant demographics*: Not described
- *Anthropometrics*:
 - Low-CHO diet group BMI: 34.5±1.8kg/m²; Mediterranean diet group BMI: 34.0±1.0kg/m²
 - Low-CHO diet group body fat percentage: 45.8±2.0%; Mediterranean diet group body fat percentage: 48.7±1.7%.
- *Location*: Italy.

Summary of Results:

Body Weight and Composition

- The diet treatment induced a significant weight loss in both groups at two months, but at the end of the study, subjects on the Atkins diet lost significantly more weight than did those on the Mediterranean diet. The Atkins groups lost -7.6±0.8kg and the Mediterranean group lost -4.9±0.6kg (P=0.014)
- At the end of the study, body fat distribution was not significantly modified in either diet group.

Cardiovascular Disease Risk Factors

- Total cholesterol, LDL-cholesterol, fasting insulin and HOMA-IR were significantly decreased in both groups at the end of two months
- Flow mediated dilation was not significantly different at the end of the two-month intervention
- Systolic blood pressure reduced significantly at two months in the low-CHO diet group, and it was significantly lower (117±3mmHg) than that of the Mediterranean diet group (125±2mmHg) (P<0.005).

Author Conclusion:

After two months, a group of subjects following the Atkins diet lost more weight than those on a Mediterranean diet. However, measures of cardiovascular risk did not differ between the diet groups.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	No
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes